

**SUPPORTING STATEMENT
FOR
Reclassification Petitions for Medical Devices
21 CFR 860.123
OMB No. 0910-0138**

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting extension of approval from the Office of Management and Budget (OMB) for the information collection requirements in the following reclassification regulation 21 CFR Section 860.123 (Attachment 1).

21 CFR 860.123 - Reporting

Requires device manufacturers to provide, in a petition for device reclassification, specification of the type of device, a statement of the action requested, and justification for the request to reclassify.

The classification regulation, 21 CFR Part 860, including subpart C, reclassification, was promulgated under the authority of 21 U.S.C. 360(e) and (f), 360d(b), 360e(b), 360j(1), and 360i(b)(1)(A) (Attachment 2).

The 1976 amendments to the Food, Drug, and Cosmetic Act (the act) provide three tiers of regulatory control for medical devices, by establishing three classes of medical devices, and requiring that all devices be classified into one of these three. The assignment of a device into a class depends upon the degree of regulatory control necessary to provide a reasonable assurance of the safety and effectiveness of the device. The amendments also provide for changing device classification. The three tiers of regulatory control are: 1) Class I - general controls, subject to sections 501 adulteration, 502 misbranding, 510 registration, 516 banned devices, 518 notification and other remedies, 519 records and reports, and 520 general provisions of the act; 2) Class II - performance standards; and 3) Class III - premarket approval.

The Safe Medical Devices Act of 1990 and the 1992 amendments (Attachment 3) amended the definition of a Class II device. Under the 1990 amendments, Class II (now identified as special controls) devices are those devices for which there is insufficient information to show that the general controls by themselves will provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards.

In addition to the mandated classification of all devices offered for sale prior to the enactment of the amendments, all post-amendments devices that are not substantially equivalent to a pre-amendments device are automatically placed in Class III by section 513(f) of the act. All pre-amendments devices that were regulated as new drugs by FDA, prior to the enactment of the amendments, are automatically placed into Class III by section 520(l) of the act. Devices in either of these two groups must have premarket approval before they can be legally marketed, unless they are reclassified.

The reclassification procedures regulation requires the submission of specific data when petitioning for reclassification. This includes a "supplemental data sheet" (Form 3427) (Attachment 4) and a "classification questionnaire" (Forms 3428 or 3429) (Attachment 5). Each of these is a series of questions concerning the safety and effectiveness of the device.

The act provides for any person to petition for reclassification of a medical device, from any class to any other class. These provisions, however, serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory burden placed on a particular device. The reclassification petition, if approved, provides an alternative route to the market in lieu of premarket approval for Class III devices; most reclassification petitions are submitted seeking reclassification of Class III devices, to avoid the need for premarket approval. Neither the act nor the regulations require that any device be reclassified.

2. Purpose and Use of the Information

The staff of the Center for Devices and Radiological Health (CDRH) is responsible for reviewing petitions for reclassification and determining whether or not the subject device will be reclassified. In some instances the FDA also submits the petition(s) to one of its medical device advisory panels for review and recommendations. The decision of whether or not to reclassify a device is primarily based upon the information contained in the petition. Under the 1976 amendments, unless petitions for reclassification were submitted to FDA, medical devices were not usually reclassified. The 1990 amendments allowed FDA to initiate reclassification.

3. Use of Information Technology and Burden Reduction

A final rule was published in the FEDERAL REGISTER of March 20, 1997 (62 FR 13429) that would, under certain circumstances, permit the agency to accept electronic submissions. The intended effect of this proposal is to permit the use of electronic technologies in a manner that is consistent with FDA's overall mission. The use of proposed electronic submissions to reduce burden may be utilized with reclassification petitions. Each petition is unique, containing information with supporting data to show why device reclassification will provide reasonable assurance of the safety and effectiveness of the device. The principal data in such a petition will typically be reports of clinical trials.

4. Efforts to Identify Duplication and Use of Similar Information

The Food and Drug Administration is the only federal agency responsible for regulating medical devices; as such, there is no duplication of effort.

Similar information to what is needed for reclassification of medical devices may exist in FDA's premarket approval files for some devices. If the submitter of a premarket approval application (PMA) is willing to make such files public, they may also be used for purposes of reclassification. If, however, the submitter of the PMA is not willing to make these files public, FDA is precluded from using the data to assist reclassifying devices by sections 520(c) and (h) of the Food, Drug, and Cosmetic Act. There is no other source of data which could be used to reclassify devices.

5. Impact on Small Business or Other Small Entities

Any individual or organization may submit reclassification petitions; the requirements are the same regardless of the firm size. FDA aids small businesses in dealing with the regulation by providing guidance and information through the Division of Small Manufacturers Assistance (DSMA) of CDRH. This office provides technical and non-financial assistance to firms, through a comprehensive program which includes on-site inspections (when requested by the firm), seminars and educational conferences, information materials, and the use of a toll-free telephone number which may be used by any firm. Other members of the Center staff are also available to respond to questions at any time.

6. Consequences of Collecting the Information Less Frequently

If the information were collected less frequently, manufacturers would not be able to take advantage of the reclassification alternative provided in the act. Petitions for reclassification are generally submitted only when a firm seeks reclassification; as discussed above, the law does not require FDA to reclassify devices.

There are no technical or legal obstacles to the collection of this information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information collection is consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60-day notice (Attachment 6) was published on September 17, 1999 (64 FR 50516). No comments were received.

The CDRH has continually maintained contact with industry. Informal discussions relating to the importance and effect of reclassification is communicated primarily through trade organizations. The consensus of our most recent contact with the organizations is that they have no problem with the program. The Center has also conveyed that reclassification saves FDA resources. The trade Organizations involved are the Health Industry Manufacturers Association (HIMA), the Food and Drug Law Institute (FDLI), the National Electrical Manufacturers Association (NEMA), and the Dental Implant Manufacturers Association (DIMA).

Health Industry Manufacturers Association
Nancy Singer
1030 15th Street, NW, Suite 1100
Washington, DC 20005
(202) 452-8240

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Food and Drug Law Institute
John C. Villforth
1000 Vermont Avenue, NW
Suite 1200
Washington, DC 20005
(202) 371-1420

National Electrical Manufacturers Association
1300 North 17th Street
Suite 1847
Rosslyn, VA 22209
(703) 841-3200

9. Explanation of Any Payment of Gift to Respondents

No payment or gift is given to respondents.

10. Assurance of Confidentiality Provided to Respondent

Data relating to this information collection is subject to release under 21 CFR Part 20, "Public Information," in determining whether documents may be disclosed under Freedom of Information.

11. Justification Sensitive Questions

The information required does not include questions about sexual behavior, attitude, religious beliefs, or any other matters which are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

The respondents to this collection of information are device manufacturers.

FDA estimates the burden of this collection as follows:

Estimated Annual Reporting Burden ¹					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	11	1	11	500	5,500
TOTALS					5,500

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

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Based on current trends, FDA anticipates that 11 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Multiplying the total reporting and recordkeeping hours (5,500) by an average rate of \$25 per hour, yields an estimate annual cost to respondents of \$137,500.

13. Estimate of the Other Total Annual Cost Burden to Respondent of Recordkeepers

The requirements of the recordkeeping associated with this regulation do not involve the expenditure of any funds for capital costs or operating and maintenance costs because any equipment used is purchased for the purposes of customary and usual business practices.

14. Annualized Cost to the Federal Government

Costs for the Federal government are minimal because the review of written agreements is conducted during routine scheduled inspections conducted every two years under the medical device Good Manufacturing Practice (GMP) regulations. Therefore, written agreements for one-half of the regulated firms (45) are reviewed each year. Instructions to investigators require examination of records for 10 customers, on average. Therefore 450 written agreements (45 x 10) are examined each year. An estimated average of 15 minutes is required for each review. Therefore, an estimated 112.5 hours are required for review of the written agreements each year.

An average full time equivalent employee is projected to cost FDA/CDRH \$89,705, which consists of the employee's salary and any overhead which accompany that employee. Therefore, the average hourly wage rate (including overhead) for an FDA/CDRH employee would be \$43.

The burden to government for this information collection is \$4,738 per year which is computed by taking the hourly average FTE cost of \$43 and multiplying it by 112.5 hours.

15. Explanation of Program Changes of Adjustment

There are no changes in the burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of reclassification of medical device actions will not be published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to not display the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exception is sought to the certification statement identified in Item 19 of OMB Form 83-I.

B. Collection of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.

LIST OF ATTACHMENTS
for
RECLASSIFICATION PETITIONS SUPPORTING STATEMENT:

1. Reclassification regulation 21 CFR Section 860.123
2. 21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), 360j(l) and 360I(b)(1)(A)
3. The Safe Medical Devices Act of 1990 and the Medical Devices Amendments of 1992
4. Supplemental Data Sheet (Form 3427)
5. Classification Questionnaire (Forms 3428 and 3429)
6. 60-day Federal Register Notice